

REMARKS

Reconsideration of this application in view of the following remarks is respectfully requested. Claims 1-58, 60 and 63-140 are pending. Claims 37-57 and 63-101 have been withdrawn from consideration pursuant to a restriction requirement. Claims 1-36, 58, 60 and 102-140 are under examination.

*Claim Rejections – 35 USC § 103*

Claims 1-3, 5-9, 10, 12, 14-21, 23-30, 32-36, 58, 60, and 102-114 stand rejected under 35 U.S.C. 103(a) as being unpatentable in view of Buncke (U.S. 5,931,855) in view of Morency (US 2003/0149447). The Office Action acknowledges that neither Buncke nor Morency disclose a barbed suture wherein the barbs have either an arcuate base or a barb cut angle from about 140 degrees to about 175 degrees. Nevertheless, the Office Action takes the positions that those features would be obvious in view of the cited references. This rejection is respectfully but strenuously traversed for the following reasons.

While both Buncke and Morency are directed to barbed sutures, neither document mentions either the configuration of the barb base, or the barb cut angle. Furthermore, and as a necessary consequence, neither document mentions that either of these parameters is relevant to the performance of a barbed suture. In notable contrast, Applicants have (a) identified the parameters of barb base configuration and barb cut angle; (b) have indicated that these parameters are relevant to the performance properties of the barbed sutures, and (c) have provided specific values for each of barb base configuration and barb cut angle which Applicants claim as their invention. In view of these facts, and for reasons expanded upon in the following remarks, Applicants respectfully contend that the claimed invention is not taught, suggested, or obvious, in view of Buncke, Morency, or the combination thereof.

The Examiner provided a rationale to support his position, which Applicants summarize as follows:

In regard to barb base configuration, the Examiner points to Morency as teaching that barbs may be rounded on both the topside of the barb (74) and underside of the barb (76) when suture is used in delicate tissue prone to tearing (citing [0040] and Fig 1G). Therefore, concludes the Examiner, it would have been obvious to one of ordinary skill in the art at the time

the invention was made to modify the device of Morency such that the base at the underside of the barbs, *i.e.*, the base which is transverse to the longitudinal axis of the body, was likewise arcuate to prevent tearing of delicate tissue.

Applicants respectfully contend that the stated rationale does not support a proper rejection under 35 U.S.C. 103(a) for the following reasons. Initially, Applicants respectfully point out that Morency contains no mention at all of the barb base. Accordingly, there is no teaching or disclosure in Morency directed to the impact that various barb base configurations may have on the performance properties of a barbed suture. Furthermore, it should be noted that Morency, even though interested in preventing tearing of delicate tissue, never mentions that the barb base should be configured in any particular way in order to minimize or otherwise impact the tearing of delicate tissue, including having the barb base be in an arcuate shape. The rejection seems to assume a connection between the shape of the underside of the barb, and the shape of the barb base. However, there is no logical reason why that connection should exist, and there is nothing in the cited prior art to suggest or support that possible connection. Thus, it would appear that the Examiner has used hindsight and supposition to create this rejection, rather than drawing from any teaching or suggestion in Morency.

To support the rejection under 35 U.S.C. 103(a) regarding barb cut angle, the Examiner takes the position that Figures 15 and 16 of Buncke show the barb, 98, being made from a blade that is characterized by having a sharp cutting edge, a base and an angle. Thus, concludes the Examiner, the barbs created from the blade must have a barb cut angle, and it would be obvious to select any of about 140 to 175 degrees, or about 152 to 165 degrees or about 152 to 163 degrees as the barb cut angle. To support this position, the Examiner asserts that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. Applicants respectfully but strenuously traverse this rejection for the following reasons.

Figures 15 and 16 are discussed at column 8 of Buncke. Applicants have reviewed the entirety of column 8 and do not see any discussion, or even any mention, of the angle of the blades used to cut a barbed suture. Furthermore, there is no mention of the angle of the barbs created by action of the blades. In looking at the Figures themselves, these are clearly schematic drawings, intended to convey and support the general topics discussed at column 8.

Those topics do not include barb cut angle. In view of this silence on the part of Buncke, Applicants respectfully contend that neither the text nor the supporting drawings teach or suggest to specify barb cut angle as a feature of a barbed suture, and certainly do not teach or suggest the ranges set forth in Applicant's claimed invention.

The Examiner notes, without reference, that it has been held that discovering the optimum or workable ranges involves only routine skill. However, Applicants understand these holdings to apply to the situation where the prior art identifies a particular parameter as being of importance, and then sets forth desired ranges for that parameter. In the present situation, the prior art has not identified the parameter of barb cut angle as being of importance, and has furthermore not identified any particular ranges for that parameter which are desirable. Thus, Applicant's respectfully contend that the holdings presumably being referred to by the Examiner do not support the rejection under 35 U.S.C. 103(a).

In view of these comments, Applicants respectfully contend that the claimed invention is not obvious under 35 U.S.C. 103(a), and accordingly reconsideration and withdrawal of the rejection are requested.

#### ***Claim Rejections – 35 USC § 103***

Claims 4, 13, 22, 31 and 115-140 stand rejected under 35 U.S.C. 103(a) as being unpatentable in view of Buncke (U.S. 5,931,855) and Morency (U.S. 2003/0149447) as applied to claims 1, 10, 19 and 28 above, and further in view of Ruff (U.S. 5,342,376). The Examiner points to Ruff as disclosing that the configuration of barbs on a barbed suture, and the surface area of those barbs, can vary depending upon the tissue in which the barbed suture is used. The Examiner then concludes that it would have been obvious to design a barbed suture having at least two sets of barbs, wherein each set has a barb size different from the other set according to Applicants' claim 4 and claims dependent thereon. Applicants respectfully traverse this rejection for the following reasons.

As a first reason, and as noted by the Examiner, claims 4, 13, 22, 31 and 115-140 ultimately depend on claims 1, 10, 19 and 28. For the reasons provided above, Applicants respectfully contend that claims 1, 10, 19 and 28 are patentable in view of the cited prior art. Accordingly dependent claims 4, 13, 22, 31 and 115-140 are likewise patentable.

As a second reason, Applicants respectfully contend that the Examiner's position is not consistent with the combined teachings of Buncke, Morency and Ruff. The Examiner has pointed to col. 4, lines 5-17. In looking at this passage, it can be seen that at col. 4, line 12, Ruff discloses that "each barb" can be made relatively short to facilitate entry into firm tissue. At col. 4, line 15, Ruff discloses that "the barbs" can be made longer and spaced farther apart to increase the holding ability in soft tissue. Applicants respectfully contend that this disclosure suggests to make the barbs one size or the other on a connector, and does not teach or suggest to mix barb sizes on a single connector.

The Examiner has also pointed to col. 5, lines 2-6. This passage, which pertains to Figure 4, states that the barbs in a tissue connector can be arranged in a nonuniform bidirectional configuration. Figure 4 illustrates such barbs, and shows multiple barbs arising from a single location on the connector, where the barbs point in different directions. Applicants respectfully contend that Ruff cannot mean to combine the disclosure of col. Lines 5-17 with this disclosure at col. 5, lines 2-6 because the resulting connector would provide "soft tissue" type barbs and "hard tissue" type barbs at the same location. The tissue itself, when the connector was inserted into the tissue, would be either soft or hard at this location of the connector, and surely not both types. Thus, given the rationale of Ruff for selecting a barb type to match the tissue type, it would not be logical to prepare a connector of the sort shown in Fig. 4 having two different types of barbs.

Applicants have looked through the disclosure of Ruff, and note that at col. 5, lines 16-19, there is a disclosure referencing Figure 5. Figure 5 shows barbs segregated into two regions along the connector where the barbs in a first region nearest a first end of the suture point away from the first end, and the barbs in a second region nearest the second end of the suture point away from the second end. However, this passage from Ruff also instructs that the barbs should have a uniform configuration (see col. 5, line 18) and, in fact, Figure 5 shows a connector having a uniform configuration of barbs, albeit bidirectional. Thus, this disclosure, and the associated Figure, are inconsistent with two different configurations according to Applicants' claimed invention.

In summary, Applicants' respectfully contend that independent claims 1, 10, 19 and 28 are patentable in view of the disclosures of Buncke and Morency, as discussed above, and

furthermore that dependent claims 4, 13, 22, 31 and 115-140 are likewise patentable in view of the combined disclosure of Buncke, Morency and Ruff. Furthermore, the combined disclosure of these three documents does not teach or suggest the invention of claims 4, 13, 22, 31 or 115-140, and the Examiner's reconsideration of the rejections in view of the foregoing comments, and withdrawal of the rejections, are respectfully requested.

***Double Patenting Rejection***

Claims 1, 19, 28 and 58 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 16, filed on 9/28/09, of copending Application No. 10/065280. In addition, claims 1, 19, 28 and 60 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22 filed on 9/28/09 of copending Application No. 10/065280. While not agreeing with this rejection, and solely to expedite prosecution, Applicants submit herewith a Terminal Disclaimer in view of US Application No. 10/065,280. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

A good faith effort has been made to place this application in condition for allowance. However, should any further issue require attention prior to allowance, the Examiner is requested to contact the undersigned at (425) 831-3090 to resolve the same.

The Director is authorized to charge any additional fees due by way of this amendment, or credit any overpayment, to our Deposit Account No. 50-2574.

Respectfully submitted,  
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